APPENDIX E

DISCUSSION ON EVALUATING/DEVELOPING SITE-SPECIFIC DERMAL ABSORPTION DATA

In some situations, it may be worthwhile to develop site-specific dermal absorption data during remedial investigations at Superfund sites. Such data would be most useful when dermal exposure contributes significantly to the overall risk and when the default assumptions may not be applicable. In the future, EPA plans to develop detailed laboratory protocols for how to conduct these experiments. To help in the interim, the discussion below offers some general principles and information sources on designing experiments and evaluating the resulting data.

Part E makes numerous references to ORD's 1992 Dermal Exposure Assessment (DEA) and is considered an extension of the principals and methods identified in DEA for Superfund sites. Section 5.1 of the DEA presents a strategy for reviewing data on dermal absorption of chemicals from an aqueous medium. Chapter 6 of the DEA discusses dermal absorption from soils. The literature in this area was and still is quite sparse. Therefore, much less detail is provided on how to evaluate soil data. These portions of the DEA should be reviewed in detail before planning dermal absorption experiments. However, some of the general principles are summarized below:

- Test skin should be healthy and intact.
- Experiments should be conducted in a manner that matches exposure conditions to the extent practical. For water contact scenarios this means using an aqueous vehicle. For soil contact scenarios, this means using a soil load on skin and particle size that matches exposure conditions. Generally, soil loading should not exceed a monolayer. Procedures should be used to ensure that the soil maintains close contact with skin throughout the experiment.
- In vitro tests should use continuous flow and infinite dose procedures.
- In vivo tests should allow periodic collection of data to demonstrate that steady state has been achieved.
- Experiments should be conducted at ambient temperatures, and volatilization should not be prevented.

Other parts or programs of EPA have published guidance on how to conduct dermal absorption studies. While these are generally specific to products rather than contaminated soils or water, they contain some potentially useful information for Superfund assessments and could be consulted for further guidance:

OPPTS Harmonized Test Guidelines. Series 870 Health Effects Test Guidelines–Final Guidelines. 870.7600 Dermal penetration, August 1998,
http://www.epa.gov/opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/

EPA's Office of Pollution Prevention and Toxic Substances: Federal Register / Vol. 64, No. 110 / page 31074. June 9, 1999. Proposed Test Rule for In Vitro Dermal Absorption Rate Testing of Certain Chemicals of Interest to Occupational Safety and Health Administration.

Similar guidance has also been developed at the international level by the Organization of Economic Cooperation and Development (OECD) and could also be consulted:

OECD (2000a). OECD Guideline for the Testing of Chemicals. Draft Guideline 428: Skin absorption: in vitro method (December 2000).

OECD (2000b). OECD Guideline for the Testing of Chemicals. Draft Guideline 427: Skin absorption: in vivo method (December 2000).

OECD (2000c). Draft guidance document for the conduct of skin absorption studies. OECD environmental Health and Safety Publications Series on Testing and Assessment No. 28 (December 2000).

OECD (2000d) Test Guidelines Program. Percutaneous absorption testing: is there a way to consensus? OECD document ENV/JM/TG(2000)5, April 2000, Paris, France.